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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,975	07/09/2002	John Collinge	20020011.ORI	1098

23595 7590 07/27/2004

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/031,975

**Applicant(s)**

COLLINGE ET AL.

**Examiner**

Jeffrey S. Parkin, Ph.D.

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 31-65 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### Restriction Requirement

#### 35 U.S.C. § 121

This application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. § 121 and 372. The regulations governing the claiming of different inventions in one national application are set forth under 37 C.F.R. § 1.141, 1.475, and 1.499. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1:

- a. Group I, claim(s) 31-33 and 64, drawn to **PrP<sup>C</sup> peptidic fragments** corresponding to amino acids 176-221.
- b. Group II, claim(s) 34, drawn to a **method of making a polyclonal antibody** to the **PrP<sup>C</sup>** protein.
- c. Group III, claim(s) 35, drawn to a **polyclonal antibody** that binds to **PrP<sup>C</sup>**.
- d. Group IV, claim(s) 36, drawn to a **method of making a monoclonal antibody** to the **PrP<sup>C</sup>** protein.
- e. Group V, claim(s) 37, drawn to a **monoclonal antibody** that binds to **PrP<sup>C</sup>**.
- f. Group VI, claim(s) 38, 39, 52, and 53, drawn to a **method of making a binding agent** capable of binding to **PrP<sup>C</sup>**.
- g. Group VII, claim(s) 40, drawn to a **binding agent** that binds to **PrP<sup>C</sup>**.
- h. Group VIII, claim(s) 41, 54, and 55, drawn to a **method of detecting PrP<sup>C</sup>** using a **polyclonal antibody**.
- i. Group IX, claim(s) 41, 54, and 55, drawn to a **method of detecting PrP<sup>C</sup>** using a **monoclonal antibody**.
- j. Group X, claim(s) 42, 56, and 57, drawn to a **method of detecting PrP<sup>C</sup>** using a **binding agent**.

- k. Group XI, claim(s) 43, 45, 47, 48, 58, and 59, drawn to a method of detecting PrP using a polyclonal antibody.
- l. Group XII, claim(s) 43, 45, 47, 48, 58, and 59, drawn to a method of detecting PrP using a monoclonal antibody.
- m. Group XIII, claim(s) 44, 46, 49, 50, 60, and 61, drawn to a method of detecting PrP using a binding agent.
- n. Group XIV, claim(s) 51, 62, and 63, drawn to a method of removing PrP<sup>C</sup> from a sample using a polyclonal antibody.
- o. Group XV, claim(s) 51, 62, and 63, drawn to a method of removing PrP<sup>C</sup> from a sample using a monoclonal antibody.
- p. Group XVI, claim(s) 51, 62, and 63, drawn to a method of removing PrP<sup>C</sup> from a sample using a binding agent.
- q. Group XVII, claim(s) 65, drawn to a kit comprising various agents for the detection of PrP<sup>C</sup>.

Concerning Groups I, III, V, VII, and XVII, each invention is directed toward structurally and functionally different compounds (e.g., peptidic fragments, polyclonal antibodies, monoclonal antibodies) or a kit comprising these various reagents. Each group will also require a separate search of the prior art. Accordingly, the groups do not share a special technical feature. Concerning the various methodology claims set forth in Groups II, IV, VI, and VIII-XVI, each group is directed toward a different scientific objective (e.g., method of making polyclonal antibodies, method of making monoclonal antibodies, method of making PrP<sup>C</sup> binding agents, method of detecting PrP<sup>C</sup>, method of detecting PrP, method of removing PrP<sup>C</sup> from a sample) that employs different scientific reagents (e.g., polyclonal antibodies, monoclonal antibodies, binding agents, hybridomas) and protocols. Separate searches will also clearly be required for each group. Accordingly, a special technical feature is not present.

In accordance with 37 C.F.R. § 1.499, applicant(s) is/are required, in response to this action, to elect a single invention to which the claims must be restricted. The claims should be

amended, where necessary, to reflect the restriction requirement and election. Applicants are also reminded that if multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto, will be considered as the main invention in the claims (refer to PCT Article 17(3)(a) and § 1.476(c)). The novelty of the instant invention appears to be directed towards peptidic fragments of the PrP<sup>C</sup> corresponding to region 176 to 221. Should applicants elect to prosecute this invention, a single method of use employing these peptides and a single method of preparing them would also be considered.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

#### ***Correspondence***

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington,

Serial No.: 10/031,975

Applicants: Collinge, J., et al.

VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

A handwritten signature in black ink, appearing to read "Jeffrey S. Parkin", with a large, stylized initial "J" and a horizontal flourish extending to the right.

Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

22 July, 2004